JUDGE JONES

07 CV 4006

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHEILA E. SCHRANK, On Behalf of Herself and All Others Similarly Situated, Plaintiff, v. GLAXOSMITHKLINE PLC, Defendant.	**CIVIL ACTION NO.** MAY 22 2007 **CLASS ACTION COMPLAINT**

Plaintiff Sheila E. Schrank ("Plaintiff"), on behalf of herself and all others similarly situated, by their attorneys, Schoengold Sporn Laitman & Lometti, P.C., for her class action complaint against defendant GlaxoSmithKline PLC ("Defendant," "Glaxo" or the "Company"), alleges as follows, upon knowledge as to herself and upon information and belief based upon review and analysis of information readily available on the Internet, and other facts as set forth herein.

NATURE OF THE ACTION

This action alleges violations of Section 349 of the New York State General Business Law ("GBL"), common law fraud, unjust enrichment and negligent misrepresentation in connection with Defendant's creation, marketing, sale and distribution of widely-used diabetes drug Avandia (rosiglitazone), which Glaxo continued to market to unsuspecting diabetics despite having access to results from numerous trials indicating that patients taking the drug suffered from 43% higher risk of suffering a heart attack. Indeed, the Company itself did a "meta-analysis" of numerous studies that showed that Avandia was associated with a 31% higher risk of adverse cardiovascular events such as heart attacks. The action is brought by Plaintiff

individually and on behalf of all those persons who have purchased and/or ingested Avandia from September 1, 2005 through May 21, 2005 to treat their diabetes.

FACTUAL ALLEGATIONS

1. Type 2 diabetes is the most common form of diabetes, afflicting 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use what it manages to produce. Further, diabetics are prone to heart problems, and indeed, two-thirds of diabetics die of heart problems.

2. Avandia, created and marketed by Glaxo, is designed to treat persons with Type 2 diabetes by helping sensitize cells to insulin, thereby greatly assisting in blood-sugar control. It also is combined with metformin and sold as Avandamet. Only one other drug like it, pioglitazone, sold as Actos and Actoplus Met by Takeda Pharmaceuticals, is sold in the United States. In 2006, Avandia represented 37% of the U.S. market for oral diabetes treatments. Thus, the U.S. market for such drugs is huge and Avandia faces only one competitor for that market.

3. Avandia had total U.S. sales of $2.2 billion in 2006, slightly less than the $2.6 billion in total U.S. sales for Actos, according to IMS Health, a healthcare information company. Approximately 13 million Avandia prescriptions were filled in the U.S. last year, with a one-month supply of Avandia selling for between $90 and $170. Avandia is critical to Glaxo, being the Company's second largest selling drug after Advair (an asthma medication).

4. As early as 2005, Glaxo performed an overview analysis of multiple Avandia trials, referred to as a "meta-analysis," and shared the preliminary results with the Food and Drug Administration ("FDA") in September 2005. Almost one year later, in August 2006, a more complete version of the meta-analysis was provided to the FDA. The results of Glaxo's analysis

showed that patients taking Avandia had a 31% higher risk of adverse cardiovascular events such as heart attack due to obstruction of blood flow.

5. Not only was Glaxo aware of the dangers posed by Avandia since as early as September 2005, but the data from these studies continued to be available to the Company. On May 21, 2007, Dr. Steven Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the *New England Journal of Medicine* of his analysis of 42 studies comprising approximately 28,000 people who took Avandia. These were on-line dababases of Glaxo studies that were available on the Internet. His meta-analysis revealed a 43% higher risk of heart attack for those taking Avandia compared to people taking other diabetes drugs or no diabetes medication: people taking Avandia suffered such adverse events at a rate of 1.99%, as opposed to 1.51% for other patients. Further, Dr. Nissen's analysis showed a 64% elevated risk of death from cardiovascular causes, although this finding did not rise to the level of statistical significance.

6. Despite Glaxo's longstanding knowledge of these dangers, Avandia's label only warns about possible heart failure and other heart problems when taken **with insulin**. Defendants failed to warn and disclose to consumers that Avandia significantly increased the risk of adverse cardiovascular events. Furthermore, the proper and effective use of Avandia by Plaintiff and the Class was impaired due to Defendant's failure to warn of Avandia's defects and Defendant's failure to properly and adequately set forth such warnings in Avandia's drug labeling.

7. Glaxo knew of these dangerous defects in Avandia from the many trials which it performed and to which it had access and from its own analysis of these studies, but it took no action to adequately warn or remedy the defects, but instead concealed, suppressed and failed to

disclose these dangers. Even in the face of Dr. Nissen's study, Glaxo continues to fail to warn of these dangers through revised drug labeling.

8. Unfortunately for Plaintiff and many members of the Class, they -- only after a period of time of taking Avandia -- have suffered injuries actually or are potentially at risk for such injuries, causing thousands of dollars in bodily damage and for medical bills and then depriving these patients of the treatment Avandia purports to provide.

9. Not only has Glaxo failed to disclose in its labeling or advertising that Avandia is actually dangerous for diabetics, the Company has represented and continues to represent that they manufacture and/or sell safe and dependable pharmaceuticals with safety as their first concern:

> Like all innovative pharmaceutical companies, we carry out a series of clinical trials to test each investigational drug for the potential to become a new medicine.
>
> * * *
>
> Phase I trials typically involve healthy volunteers. ***These trials study the safety of the drug and its interaction with the body***, for example, its concentration and duration in the blood following various doses, and begin to answer such questions as whether the drug inhibits or amplifies the effects of other medicines that might be taken at the same time.
>
> Phase II studies enrol patients with the illness an investigational drug is designed to treat. These trials evaluate whether the drug shows favourable effects in treating an illness and seek to determine the proper dose. They provide an opportunity to explore the therapeutic potential of the drug in what may be quite different illnesses. ***The evaluation of safety continues.***
>
> If Phase II results have been encouraging, Phase III trials, the largest part of a clinical-development program, go forward. ***Phase III trials are designed to provide the substantial evidence of efficacy and safety required***, in addition to data from earlier-phase trials, before regulatory agencies will approve the investigational drug as a medicine and allow it to be marketed.

http://www.gsk.com/research/clinical/index.html (Emphasis supplied).

10. Defendants have also strongly touted their commitment to improving the quality of life: "We have a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better and live longer." http://www.gsk.com/about/index.htm.

11. Based on these representations, upon which Plaintiff relied, including the omission from the Avandia labeling of the danger of increased risk of adverse cardiovascular events as a result of taking the drug, Plaintiff and other Class members purchased and took Avandia, believing that the drug would be safe and effective.

12. In fact, however, Avandia poses significant safety risks due to defects in its chemical design.

13. To date, Glaxo has failed to warn or inform its consumers of the known defects in Avandia that can lead to increased risk of cardiovascular events, fraudulently concealed these defects and made misrepresentations to the damage and detriment of Plaintiff and the other Class members.

14. As a result of Defendant's omissions and/or misrepresentations, diabetic patients who took Avandia have suffered damages, including financial and physical damages.

JURISDICTION AND VENUE

15. The claims asserted herein arise under and pursuant to alleged violations of Section 349 of the GBL, common law fraud, unjust enrichment and negligent misrepresentation. The action is brought by Plaintiff individually and on behalf of all those persons who purchased and/or ingested Avandia from September 1, 2005 through May 21, 2007.

16. This Court has jurisdiction over the subject matter of this action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. §1332, diversity jurisdiction pursuant to 28 U.S.C. §1332(d)(2) and supplemental jurisdiction pursuant to 28 U.S.C. § 1367. Plaintiff and many other Class members are citizens of states different than that of one or more Defendants, and the matter in controversy exceeds the sum of $5,000,000, exclusive of interests and costs.

17. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because Defendant transacts business in this District, is subject to personal jurisdiction in this District, and therefore is deemed to reside in this District, within this State. Many of the acts and transactions alleged herein, including the dissemination of materially false and misleading material including, *inter alia*, Avandia labels, occurred in this District. Additionally, Defendant distributes and injects Avandia within the stream of commerce into this District. Defendant directly and through its agents, regularly transacts business and otherwise derives substantial revenue in New York and the United States.

18. This Court is appropriate for the litigation of the claims of all members of the Class because Defendant conducts substantial and continuous business in this State. Defendant conducts business activities relevant to this action and no other state's governmental policies or interests with the litigation outweigh those of this State.

PARTIES

19. Plaintiff Sheila E. Schrank ("Schrank") is a resident of New York, Nassau County, and purchased Avandia in order to treat her diabetic condition.

20. In February of 2006, plaintiff Schrank, who suffers from diabetes, was took Avandia to treat her condition. She was then admitted to Long Island Jewish Hospital after suffering arrhythmia. She remained overnight at the hospital, where her doctors ceased her

regimen of Avandia. She was placed on a treatment of insulin, and her arrhythmia has subsequently disappeared.

21. As a result of Defendant's omissions and/or misrepresentations related to Avandia's defects, plaintiff Schrank has sustained damages.

22. Defendant GlaxoSmithKline, PLC ("Glaxo" or the "Company") is a British corporation with its principal place business in the United States at One Franklin Plaza, Philadelphia, Pennsylvania 19101. Glaxo, together with its subsidiaries, engages in the creation, discovery, development, manufacture, and marketing of pharmaceutical and consumer health-related products. It operates in two segments, Pharmaceuticals and Consumer Healthcare. The Pharmaceuticals segment manufactures prescription drugs and vaccines that are used in various therapeutic areas, including central nervous system, respiratory, anti-viral, anti-bacterial, oncology and emesis, metabolic, cardiovascular, and urogenital. Headquartered in the UK and with operations based in the US, Glaxo is an industry leader, with an estimated seven per cent of the world's pharmaceutical market.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

23. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(b)(3) on behalf of herself and all members of the proposed class defined as follows: all those persons who purchased or ingested Avandia from September 1, 2005 through and including May 21, 2007 (the "Class"). Excluded from the Class is Defendant, its parents, subsidiaries, affiliates, agents and representatives, including its registered dealers and its officers and directors at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendant has or had a controlling interest.

24. The members of the proposed Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are millions of Class members who have purchased or ingested Avandia. Class members may be identified through discovery from records maintained by Defendant.

25. Plaintiff's claims are typical of the claims of the Class, as all Class members were and are similarly affected by Glaxo's wrongful conduct in violations of the GBL and common laws that are complained of herein. Plaintiff and each of the Class members purchased and/or ingested Avandia, which may cause increased risk of cardiovascular events. Defendant knowingly concealed, suppressed, and/or fraudulently misrepresented/omitted Avandia's defects, with the intent that Plaintiff and other Class members rely thereon. Plaintiff and the other Class members have sustained substantial damages, resulting from Defendant's omissions and/or misrepresentations related to Avandia's defects.

26. Plaintiff will fairly and adequately represent and protect the interests of the other Class members and has retained counsel competent and experienced in class action and consumer fraud litigation. Plaintiff and their counsel are aware of no conflicts of interest between Plaintiff and the other Class members.

27. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:

(a) whether Avandia was created and designed with defects that increase patients' risk of adverse cardiovascular events;

(b) whether Avandia increase patients' risk of adverse cardiovascular events, as a result of its defects;

(c) whether Defendant knowingly failed to disclose and warn of Avandia's defects with the intent that others rely upon such concealment, suppression or omission;

(d) whether Defendant used or employed unconscionable commercial practices in connection with the sale of Avandia;

(e) whether Plaintiff and members of the Class are entitled to entry of final injunctive relief compelling Defendant to recall Avandia;

(f) whether Plaintiff and members of the Class are entitled to entry of final injunctive relief compelling Defendant to fully and adequately inform consumers of Avandia's defects;

(g) whether Plaintiff and members of the Class are entitled to actual damages representing the ascertainable loss of money and/or property that have been and/or will be suffered by Plaintiff and members of the Class as a result of Avandia's defects;

(h) whether Defendant intentionally or negligently misrepresented material facts concerning Avandia's defects;

(i) whether Defendant was unjustly enriched by their misrepresentations and fraud;

(j) whether Class members are entitled to monetary damages and injunctive relief;

(k) whether the Court should establish a constructive trust funded by the benefits conferred upon the Defendant by its wrongful and unlawful conduct;

(l) whether the GBL and the common laws were violated by Glaxo's conduct as alleged herein;

(m) whether Defendant had a duty to disclose material facts concerning the serious problems that would inevitably result from its inherently defective Avandia design;

(n) to what extent the Class has sustained damages; and

(o) to what extent Defendant should be held to account for its wrongful conduct.

28. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Given the common defects present in Avandia, and the uniform misrepresentations and omissions not disclosed to the Class, Plaintiff is not aware of any difficulties in managing the action as a class action

29. The prosecution of separate actions can create a risk of inconsistent or varying adjudications with respect to individual members of the Class which could establish incompatible standards of conduct for Defendant. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them.

FIRST CLAIM

Violation of the New York General Business Law § 349

30. Plaintiff repeats and reiterates the allegations as set forth above as if set forth fully herein.

31. Section 349 of the New York's General Business Law states:

> Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful.

32. As set above, the deceptive, acts, practices, and the false representations and omissions made by Glaxo to Plaintiff and the other Class members concerning the safety of Avandia were disseminated into New York in the course of conducting their business, trade and services in New York, including but not limited to statements made on the Company's website and omissions of material warnings from Avandia's labeling. Defendant's misrepresentations and omissions were likely to mislead reasonable consumers acting reasonably under the circumstances. Defendant's statements, omissions and deceptive scheme, directed at consumers, mislead Plaintiffs and other Class members.

33. Glaxo's conduct and actions, as described above, constitute deceptive business practices in violation of the GBL.

34. The damages sustained by Plaintiffs and the other Class members were a direct and foreseeable result of, and were proximately caused by Defendants' deceptive business practices.

35. As a result of Glaxo's actions, Plaintiff and other Class Members have been injured and damaged in an amount to be determined at trial.

SECOND CLAIM

Common Law Fraud

36. Plaintiff repeats and realleges the allegations as set forth above as if set forth fully herein.

37. The above described conduct and actions constitute common law fraud by way of misrepresentations, concealment and omissions of material facts made by Glaxo in the sale and distribution of Avandia which are the subject of this action.

38. Glaxo, upon information and belief, made the above-described misrepresentations, concealment and omissions of material facts concerning its sales and maintenance service practices with full knowledge that they were false and misleading or with reckless disregard of the truth.

39. Defendant intended that the Plaintiff and the other members of the Class rely upon the above-described misrepresentations, concealment and omissions.

40. Defendant's misrepresentations, concealments and omissions concerning the safety and effectiveness of Avandia were material in Plaintiff's and the other Class member's decision to purchase and/or ingest Avandia.

41. Plaintiff and other Class members justifiably relied upon such misrepresentations, concealment and omissions to their damage and detriment.

42. The damages sustained by Plaintiffs and the other Class members were a direct and foreseeable result of, and were proximately caused by, Defendants' misrepresentations, concealment and omissions.

43. Defendant's conduct was willful, wanton, and reckless. Based on the intentionally dishonest nature of Defendant's conduct, which was directed at the Class and at the public generally, Defendant should also be held liable to the Class for punitive damages in an amount to be determined at trial.

THIRD CLAIM

Unjust Enrichment

44. Plaintiff repeats and reiterates the allegations as set forth above as if set forth fully herein.

45. As a result of Glaxo's materially false and misleading statements and failure to disclose the truth concerning Avandia's defects and dangers, Glaxo has profited and benefited from the sale of Avandia. Defendant was unjustly enriched in that Avandia did not perform as represented to Plaintiff and the Class, in fact representing a greater health risk than other diabetes treatments.

46. By purchasing Avandia in ignorance of its undisclosed dangers, Plaintiff and the Class have conferred a substantial monetary benefit upon Glaxo, thereby unjustly increasing its wealth.

47. Glaxo has benefited and been unjustly enriched by the above alleged conduct. Glaxo has sold, and continues to sell, Avandia in its defective state, thereby reaping benefits and profits from consumers.

48. Defendant should be required to disgorge this unjust enrichment.

FOURTH CLAIM

Negligent Misrepresentation

49. Plaintiff repeats and reiterates the allegations as set forth above as if set forth fully herein.

50. At all times relevant hereto, Glaxo had a duty to manufacture and distribute safe and effective pharmaceutical products, and had a further duty to disclose to Plaintiff and other consumers any dangers, defects or nonconformities.

51. At all times relevant hereto, Glaxo breached the aforesaid duty of disclosure by representing, either affirmatively or by omission that the aforesaid defects did not exist, when in fact, Avandia posed a greater risk to patients of adverse cardiovascular events as set forth above.

Defendant negligently misrepresented to Plaintiff and the Class members what it already knew -- that Avandia posed a greater risk for such adverse events.

52. Defendant's representations of the safety of Avandia were material in Plaintiff's and other members of the Class decision to purchase or ingest Avandia.

53. Plaintiff and the Class justifiably relied on Defendant's misrepresentations in purchasing or ingesting Avandia.

54. The damages sustained by Plaintiffs and the other Class members were a direct and foreseeable result of, and were proximately caused by, Defendants' negligent conduct and misrepresentations.

55. As a result of Defendant's actions, Plaintiff and other Class members have been damaged and injured in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and Plaintiff's counsel as Lead Counsel, and certifying Plaintiff as Class representative under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory and punitive damages in favor of Plaintiff and the other Class members against Defendant for all damages sustained as a result of Defendant's wrongdoing, including violation of the GBL, in an amount to be determined at trial, including interest thereon;

(c) Requiring Defendant to account for and/or pay in damages to Plaintiff and the Class the amounts by which Glaxo was unjustly enriched due to its wrongful

conduct;

(d) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees, as well as incidental and consequential damages;

(e) Awarding injunctive relief by ordering Glaxo to issue corrective actions including notification and recall, and imposing a constructive trust upon monies obtained by Glaxo as a result of the alleged wrongful conduct;

(f) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: May 22, 2007

Respectfully submitted,

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